K091414 P1/6

# 510(k) Summary

MAR 11 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**1. Submitter's Name: BioCare Corporation**

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**Contact person:** Judy Wei / Administrator

OCT 21 2009

**2. Device Name and Classification**

**Trade name:** vTrust™ Noninvasive Blood Pressure Monitor, Model 701DH series

**Common/Usual name:** Blood Pressure Monitor

**Classification name/Code:** Noninvasive Blood Pressure Measurement System-DXN

**Classification Panel:** Circulatory System Devices Panel (74)

**Device Class:** II

**3. Predicate Device**

The predicate device is CSI 507 non-invasive vital signs monitor(K910852) marketed by Criticare Systems, Inc.

**4. Device Description**

The BioCare vTrust 701DH NIBP monitor is a compact, battery-powered monitor which measures noninvasive blood pressure (systolic, diastolic and mean arterial pressure) and pulse rate based on the principle of plethysmography (oscillometric on inflation).

The oscillometric method detects volume displacements within the artery and senses pressure variations within the blood pressure cuff during inflation. The measurement is more quickly and with less patient discomfort than with monitors which measure NIBP during cuff deflation. Cycle time function enables you to pre-set measurement intervals. User can set alarm limits by selectable for high or low range.

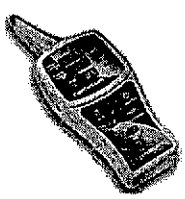
## 5. Intended Use

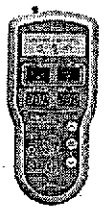
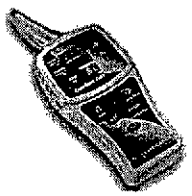
This equipment is intended to be use only by qualified medical providers in conjunction with established medical protocols. It is not intended for use in an MRI environment, or in an air transport environment.

## 6. Summary of Technological Characteristics of the Device Compared to the Predicate Device

Both vTrust 701DH blood pressure monitor and 507 non-invasive vital signs monitor is intended to be used in measuring human's Systolic, Diastolic and Pulse rate by oscillometric method. They share similar features and specifications. Performance characteristics of both devices are in accordance with ANSI/AAMI SP-10: 2002.

The substantial equivalence between vTrust 701DH and 507 non-invasive vital signs monitor can be evaluated from several aspects as listed in below Table.

| Items | Proposed device | Predicate device | Similarities | Differences |
|---|---|---|---|---|
| Device name | vTrust 701DH non-invasive blood pressure monitor  | 507 non-invasive vital signs monitor  | | |
| Device Classification | Class II | Class II | Equivalent | Negligible |
| Classification Panel | Cardiovascular | Cardiovascular | Equivalent | Negligible |
| Intended Use (Indications for use) | Monitor non-invasive blood pressure and pulse rates | Monitor non-invasive blood pressure and pulse rates | Equivalent | Negligible |
| Anatomical sites | Upper arm or limb | Upper arm or limb | Equivalent | Negligible |
| **Device Description** | | | | |
| Technology - measurement methodology | Oscillometric measure upon inflation | Oscillometric measure upon inflation | Equivalent | Negligible |
| Materials | Cuff: neoprene (non-latex) | Cuff: neoprene (non-latex) | Equivalent | Negligible |
| Energy used | Recharge NiMH battery or AC adapter | Recharge NiMH battery or AC adapter | Equivalent | Negligible |
| Weight | 650 g | 630 g | | |
| Dimensions (H*W*D) mm | 190(H) × 90(W) × 50(D) | 190(H) × 95(W) × 45(D) | | |
| Memory | 100 measurements | 100 measurements | Equivalent | Negligible |

| Items | Proposed device | Predicate device | Similarities | Differences |
|---|---|---|---|---|
| Device name | vTrust 701DH non-invasive blood pressure monitor  | 507 non-invasive vital signs monitor  | | |
| **Descriptive characteristics** | | | | |
| **Inflation & deflation** | Automatic control | Automatic control | Equivalent | Negligible |
| Display | LCD / LED | LED | | |
| Parameters | SYS DIA MAP HR | SYS DIA HR | | |
| STAT mode | **5 min of continuous readings** | **5 min of continuous readings** | Equivalent | Negligible |
| **Automatic Measurement Cycles** | 1, 2, 3, 5, 10, 15, 30, 60min | 5, 10, 15min | | |
| Auto shutoff | 20 min after last key operation | 20 min after last key operation | Equivalent | Negligible |
| System output | RS 232-compatible; digital; mini-din connector | RS 232-compatible; digital; mini-din connector | Equivalent | Negligible |
| **Performance specifications** | | | | |
| Standards met | **ANSI/AAMI SP-10: 2002, IEC-60601-1, IEC-60601-1-2, ISO 10993** | **ANSI/AAMI SP-10: 1992, IEC-60601-1, IEC-60601-1-2, ISO 10993** | Equivalent | Negligible |
| Operating environment | Temp: 0°~45℃(32°F~133°F) RH:15% to 90%, non-condensing | Temp: 0°~45℃(32°F~133°F) RH:15% to 90%, non-condensing | Equivalent | Negligible |
| Storage environment | Temp: -10°~50℃(14°F~122°F) RH:15% to 90%, non-condensing | Temp: -5°~55℃(23°F~131°F) RH:15% to 90%, non-condensing | | |
| Measurement range | Pressure: 30-300 mmHg; Pulse: 30-300 beats/min | Pressure: 30-300 mmHg; Pulse: 30-300 beats/min | Equivalent | Negligible |
| Resolution | 1 mmHg | 1 mmHg | Equivalent | Negligible |
| Accuracy | Pressure: ±2mmHg or 2% of reading; Pulse: ±2 bpm or ±2% of reading | Pressure: ±2mmHg or 2% of reading; Pulse: ±2 bpm or ±2% of reading | Equivalent | Negligible |

The differences between the two devices list as: weight, dimensions, display, parameters, cycle time. There are no significant differences that affect the safety and effectiveness. Therefore, BioCare vTrust 701DH non-invasive blood pressure monitor is substantially equivalent to the legally marketed device CSI 507 non-invasive vital signs monitor, K910852.

## 7. Determination of Substantial Equivalence is based on an assessment of Performance Data

The performance test protocols and data analysis are following "ANSI/AAMI SP10: 2002" standard. In this part, the substantial equivalence is demonstrated by showing conformance to performance requirements in the SP-10 standard. The pressure transducer accuracy and overall system effectiveness were determined and compared to the preset criteria.

### ➢ Summary of performance testing-Bench & Clinical results

| Clause | Performance Characteristics | Max. permissible error or acceptance criteria | Max. deviation | Passed/ Failed | Reference to documentation |
|---|---|---|---|---|---|
| 4.2 | Environmental performance and stability | | | | |
| 4.2.1 | Storage conditions:<br>[23°F(-5℃)] for 24 hrs;<br>[122°F(50℃)] for 24 hrs;<br>RH: 90% (noncondensing) | ≦± 3 mmHg(±0.4 kPa)<br>≦± 4 mmHg for in use | -3.4 mmHg | Passed | T-0406-004 |
| 4.2.2 | Operating conditions:<br>Temp: 50°F(10℃)~ 104°F(40℃);<br>RH: 15~90% (noncondensing);<br>Bar. 105kPa~80kPa (790mmHg~600mmHg) | ≦± 3 mmHg(±0.4 kPa)<br>≦± 4 mmHg for in use | ± 3 mmHg | Passed | T-0406-004 |
| 4.2.3 | Vibration and shock:<br>ISTA-standard drop and vibration test<br>IEC 60601-1, sections 21.5 & 21.6 | ISTA-1A: 14,200 vibratory impacts; drop test-10 drops; before and after transportation test within ±5 mmHg of the average reading. | no visible damage; SD ≦8 mmHg | Passed | T-0406-012 |
| 4.2.4 | Stability | | | | |
| 4.2.4.1 | Voltage range:<br>Battery-powered devices-indication of battery condition | Red light: low battery;<br>Blue light: batteries are charging;<br>Green light: fully charged | <8.2VDC<br>8.2~8.4VDC | Passed | PS-1040245-T |
| 4.2.4.2 | Life:<br>Maintain the safety and performance characteristics for 10,000 full-scale cycles<br>Adult mode: 150 mmHg;<br>Neo. mode: 75 mmHg | ≦ 3 mmHg(±0.4 kPa) | 2 mmHg | Passed | T-0406-004 |
| 4.2.5 | Electromagnetic compatibility | complied with EC 60601-1-2 (EMC) | | Passed | Section 17 |

| Clause | Performance Characteristics | Max. permissible error or acceptance criteria | Max. deviation | Passed/ Failed | Reference to documentation |
|---|---|---|---|---|---|
| 4.3 | Safety requirements | | | | |
| 4.3.1.1 | Maximum cuff pressure:<br>Adult: 300mmHg; neonate: 150 mmHg | NIBP pressure calibration:<br>Safety test:<br>Release pressure before <320 mmHg | <310 mmHg | Passed | PS-1040245-T |
| 4.3.1.2 | Release rate:<br>Rapid exhaust: 260~15 mmHg ≦10s<br>150~5 mmHg ≦5s | NIBP pressure calibration:<br>Speed test:<br>Deflation >25 mmHg/sec | deflate at 25 mmHg/sec | Passed | PS-1040245-T |
| 4.3.2 | Electrical safety: | IEC 60601-1, 1988; Amendment 1, 1991; & Amendment 2, 1995. | | Passed | Section 17 |
| 4.4 | Performance | | | | |
| 4.4.3 | Electronic manometers | | | | |
| 4.4.3.1.A | Range: 0 mmHg to at least 260 mmHg by visual inspection | NIBP pressure calibration | 0~300 mmHg | Passed | PS-1040245-T |
| 4.4.3.2.A | Resolution: 1 mmHg by visual inspection | NIBP pressure calibration | 1 mmHg | Passed | PS-1040245-T |
| 4.4.3.3.A | Accuracy of pressure measurement:<br>Ambient temp 10℃~40℃; RH: 15%~90%<br>**Pressure stages: 50, 100, 150, 200, 250, 300 mmHg** | ≦± 3 mmHg(±0.4 kPa) or 2% of the reading;<br>≦± 4 mmHg for in use | ± 3 mmHg | Passed | T-0406-003 |
| 4.4.3.4.A | Repeatability<br>Cuff-Link simulator test for stability and reproduction of performance<br>Adult: SYS120/DIA80/MAP90 mmHg, 80 BPM<br>Neo: SYS80/DIA50/MAP62 mmHg, 120 BPM | Average difference≦± 5 mmHg | 5 mmHg | Passed | T-0406-003 |
| 4.4.3.6.A | Leakage:<br>Ambient temp 15℃~25℃; RH: 20~85%<br>Pressure stages: 50, 100, 150, 200, 250 mmHg, wait at least 60 s before reading the values. | ≦6 mmHg/min | 1.2 mmHg/min | Passed | T-0406-003 |
| 4.4.4.B | Pressure transducer accuracy:<br>Ambient temp 10℃~40℃; RH: 15%~90%<br>**Pressure stages: 50, 100, 150, 200, 250, 300 mmHg** | ≦± 3 mmHg(±0.4 kPa) or 2% of the reading<br>≦± 4 mmHg for in use | ± 3 mmHg | Passed | T-0406-003 |
| 4.4.5.B | Overall system efficacy-clinical testing (auscultatory method as the reference Std.) no fewer than 85 subjects with a minimum of 255(=3*85) observations | For systolic and diastolic: mean≦± 5 mmHg;<br>SD ≦8 mmHg | Mean: Sys/Dia 3.4/-4.5 mmHg; | Passed | Section 20 |

| Clause | Performance Characteristics | Max. permissible error or acceptance criteria | Max. deviation | Passed/ Failed | Reference to documentation |
|---|---|---|---|---|---|
| | of 255(=3*85) observations | | SD: Sys/Dia 5.23/4.64 mmHg | | |
| 4.5 | Requirements for inflation source and pressure control valves | | | | |
| 4.5.1 | Inflation source: pressure~300mmHg≦10s | NIBP pressure calibration: Speed test: Inflation >5 mmHg/sec | inflate at 5 mmHg/sec | Passed | PS-1040245-T |
| 4.5.4.3.B | Automated valves-Release rate: rapid exhaust with fully-opened valve | 260mmHg →15mmHg ≦10 sec or 150mmHg →5mmHg ≦5 sec | deflate at 25 mmHg/sec | Passed | PS-1040245-T |
| IEC 60601-2-30 | Automatic cycling function<br>1. In long term automatic mode (normal condition)<br>Adult 120/80(90)[SYS/DIA(MAP)]--long term<br>Neonate 80/50(62)[SYS/DIA(MAP)]--long term<br>2. In long term automatic mode (single fault condition)<br>3. In short term automatic mode (stat mode) | 1. deflated time ≧30 sec; mean≦± 5 mmHg;<br>2. deflated time ≦30 sec; release cuff pressure to below 15mmHg(adult)/ 5mmHg(neo.);<br>3. deflated time≧2sec. after each determination | 1. average for adults 34 sec / for neonates 42 sec; –4mmHg;<br>2. <15sec, safety activates;<br>3. average for adults 3 sec / for neonates 8 sec; –4mmHg | Passed | T-0406-011 |

## 8. Conclusions

The BioCare vTrust 701DH non-invasive blood pressure monitor has the same intended use and similar technological characteristics as the CSI 507 non-invasive vital signs monitor (K910852) marketed by Criticare Systems, Inc. Moreover, performance testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the BioCare vTrust 701DH non-invasive blood pressure monitor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

BioCare Corporation
c/o Ms. Judy Wei
Administrator
4F, No.12, Lane 5, Sec. 2, Nanshan Rd.
Lujhu Township
Taoyuan County 33852, Taiwan

OCT 21 2009

Re: K091414
Trade/Device Name: vTrust™ Noninvasive Blood Pressure Monitor Model 701DH series
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 24, 2009
Received: August 27, 2009

Dear Ms. Wei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K091414

Device Name: vTrust Blood Pressure Monitor, Model: 701DH Series

Indications For Use:

The BioCare vTrust 701DH NIBP monitor is a compact, battery-powered monitor which measures noninvasive blood pressure (systolic, diastolic and mean arterial pressure) and pulse rate based on the principle of plethysmography (oscillometric on inflation).

This equipment is intended for use only by qualified medical providers in conjunction with established medical protocols. It is not intended for use in an MRI environment, or in an air transport environment.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use ☒ (21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091414